

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PRAECIS PHARMACEUTICALS, INC.
SECURITIES LITIGATION

Civil Action No. 04-12581 GAO

**LEAD PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION
TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT**

Lead Plaintiffs Kellie Seringer, the City of Dearborn Heights Police and Fire Retirement System, George Ladikos and Edward G. Bourne (collectively, "Plaintiffs"), submit the following memorandum of points and authorities in opposition to Defendants' Motion to Dismiss Plaintiffs' Consolidated Amended Complaint, filed September 12, 2005 ("Def. Mem.")

INTRODUCTION

This representative action is brought on behalf of all purchasers of Praecis Pharmaceuticals, Inc. ("Praecis" or the "Company") securities between November 25, 2003, and December 6, 2004, inclusive (the "Class Period"). Plaintiffs allege that they were injured as a result of violations of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934 committed by defendants Praecis, Malcom Gefter, William Heiden, Kevin McLaughlin, and Edward English (collectively, "Defendants"). ¶1, 22-25.¹ Plaintiffs' allegations concern materially false and/or misleading statements² made with respect to the market for and the marketing, projected sales, and initial success of Plexanis, a palliative drug to be taken by men with advanced prostate cancer.

Defendants' motion to dismiss argues, in essence, that Plaintiffs' theory of the case does not make sense: that it was not logical for Defendants to hire and train a sales force to sell a product they knew was doomed from the start. See Def. Mem. at 1-2.³ However, Plaintiffs do allege a motive

¹ All ¶___ citations are to the Consolidated Amended Complaint ("CAC") filed in this action.

² Defendants restate the complaint's operative allegations as 18 non-actionable statements. See Def. Mem. at Ex. A. Not surprisingly, their characterization is less than accurate: Defendants convert misstatements of current or historical fact to forward-looking statements e.g., ¶¶108-109, 114, 120-121, 127, 132; absurdly, they even list the bare fact that they filed Praecis's Form 10-Q for Q1 2004 on May 10, 2004, ¶119, as a alleged misrepresentation. Whereas the Court must evaluate the allegations of the complaint, not Defendants' versions of them, Ex. A should be stricken or ignored.

³ Defendants overstate applicable pleading requirements. Plaintiffs need only allege that their injuries were caused by the making of materially false and/or misleading statements with the requisite scienter – not that the scheme was either logical (see No. 84 Employer-Teamster Jt. Council Pension Trust Fund v. Am. West Holding Corp., 320 F.3d 920, 944 (9th Cir. 2003)(reversing finding that scheme was "illogical" because those making misrepresentations did not sell any stock)) or successful. See Danis v. USN Comms., 73 F. Supp. 2d 923, 940 (N.D. Ill. 1999) ("plaintiffs need not allege that the individual defendants were successful in their scheming, only that they planned to defraud").

recognized by courts within this Circuit. For seven years, Defendants devoted substantial financial resources⁴ to bring Plenaxis, Praecis's first and only FDA-approved product, to market. Thus, Praecis's corporate viability was predicated upon the success of its premier effort.⁵ In addition to this powerful motive, and more than \$__ million of Class Period stock sales by Praecis executives,⁶ throughout the Class Period, Defendants were contemporaneously aware of facts contrary to their representations – thereby rendering various misstatements recklessly and/or knowingly false.⁷

Specifically, Defendants issued a series of false and misleading statements aimed at giving the impression that Plenaxis, which was approved with a highly-restrictive, “black box” warning,⁸ was a viable drug with a significant market. At the start of the Class Period, during a televised interview on CNBC, Defendant Geftter brashly claimed that the market for Plenaxis was \$180 million - \$360 million (¶109), although he knew that was not the case.⁹ Specifically, Plenaxis could only be sold to those patients who were in the advanced stages of prostate cancer **and** who had

⁴ Praecis's Form 10-K for 2003 (Defs.' App. Ex. 13 p. 2), filed March 15, 2004 (see ¶117), indicated: (a) Praecis incurred approximately \$156 million in R&D expenses in 2001-2003, alone, primarily on Plenaxis; (b) clinical program spending on Plenaxis commenced in 1996. Id. at 26.

⁵ See Aldridge v. A.T. Cross Corp., 284 F.3d 72, 84 (1st Cir. 2002) (“the CrossPad product line was very important to Cross...defendants were quoted as stating that the CrossPad would be the primary driver of PCG's growth”); Sekuk Global Enterprises v. KVH Inds., Inc., 2005 WL 19224202, at *15 (D.R.I. Aug. 11, 2005) (“KVH's reliance on the success of the A5 served as a strong motive for the purported fraud;” “KVH invested \$19.5 million in...the A5, and one can infer that it sought to recoup its significant investment in this new technology”).

⁶ ¶117 (Geftter sold 600,000 shares valued at more than \$4.1 million – 300,000 shortly after he misstated the size of the market for Plenaxis on national television and 300,000 the week after Defendants falsely forecast Plenaxis sales of \$10-20 million for 2004.

⁷ Additionally, with respect to the forecasts made in January and April 2004, as set forth herein, while Defendants were willing to risk patients' lives to reach projected sales figures, the sales force and physicians were not. Now, to avoid liability to investors, Defendants claim that they warned that sales efforts might fail and physician acceptance may not occur. Def. Mem. at 15-16. The “safe harbor” does not immunize such despicable deceit.

⁸ The most serious of warnings for an approved drug, the FDA required that Plenaxis only be administered after physicians enrolled in a safety program and patients executed informed consents. Because of potential loss of consciousness, physicians had to monitor patients for 30 minutes after each injection of Plenaxis. ¶¶2, 57-59, 105.

⁹ Geftter's inaccurate description of the size of the relevant market for Plenaxis was parroted by Marc Garnick, Praecis's Chief Medical Officer, during an investor conference call. ¶108.

“severe” symptoms **and** who “opted” against surgical castration – a much smaller sub group of the “severe” group.¹⁰ ¶¶2, 42, 46. Additionally, to further assure safe use of the drug, Plenaxis would only be available to physicians who enrolled in the Plenaxis User Safety (PLUS) Program. ¶105. Nevertheless, when asked about life-threatening side-effects, Gefer minimized the potential risk. (Def. App.; Ex. 3 at 2).¹¹ Defendants’ knowledge that the market for Plenaxis was smaller than stated is also demonstrated by the facts that: (1) physicians had prescribed a competing drug, Lupron, for 15 years; unlike Plenaxis, it did not have onerous FDA “black box” restrictions and was proven to be profitable for urologists (¶¶45, 50); (2) from the very outset of training, sales staff were told to suggest use of the drug for less severe cases, outside of FDA-approved indications. ¶¶62, 66.

In January 2004, with knowledge of these facts and the additional fact that Plenaxis field sales would not commence until early Q2 of 2004, Defendants forecast that Praecis would recognize significant revenue from the sales of Plenaxis in 2004, between \$10 million and \$20 million. ¶113. Despite having no reasonable basis for this forecast-based upon internal sales expectations, ¶¶67-68, Defendants confirmed it at the end of April – even though Q1 2004 sales were dismal. See ¶¶69-70, 120 (initial stocking orders by distributors were a paltry \$400,000 – a few vials per week; physicians immediately complained that the 30-minute observation period tied up treatment rooms and that Defendants’ marketing wrongfully minimized side effects).

¹⁰ A 2002 study by the American Urologic Association found that only 7.3% of the total prostate cancer patients had severe symptoms. ¶46. Under the FDA’s limitations, Plenaxis could only be prescribed to advanced prostate cancer sufferers who also had the following “severe symptoms” -- Ureteral Obstruction, Bladder Neck Outlet Obstruction, and Syncope Cord Compression. ¶ 87.

¹¹ **Bartiromo:** What were the incidents? I have in the wires here it says three of the men experienced serious allergic reactions, one lost consciousness? **Gefer:** That's correct. Well, the degree of allergic reactions range from extremely mild, which represents itching or hives. And the most serious one was a lowering of blood pressure that caused fainting. But it's more important to point out there were no hospitalizations, no deaths, and all of these were treated and resolved relatively simply by the attending physician.

Although Defendants indicated in May 2004 that they could no longer confirm the 2004 revenue forecast, ¶¶80-81,¹² they continued to falsely report successful marketing of Plenaxis. For example, in July 2004, Defendants claimed that a fully-trained staff was engaged in sales efforts. ¶127. In fact, the sales force had already begun to walk off the job because they refused to market Plenaxis “off-label,” as urged by Defendants. Specifically, after Defendants repeatedly directed experienced sales representatives to understate the potential life-threatening side effects of Plenaxis to doctors and ignore the FDA’s strict restrictions on patient eligibility,¹³ there was substantial sales force attrition. ¶¶90, 94-96. Even worse, complaints about unethical marketing tactics were ignored, rejected or met with termination. ¶¶28, 72-74. By the second half of 2004, inexperienced sales people were hired to replace the veterans who left – and sales plummeted. ¶¶6, 96, 98.

Defendants’ description of physician reaction to Plenaxis was similarly false and misleading. While Defendants stated that there was a “growing base of repeat subscribers,” “physicians are pleased with the results” of Plenaxis treatment, and that physicians were “identify[ing] new patients for Plenaxis therapy,” ¶132, in fact, the opposite was true. Praecis was experiencing significant returns of Plenaxis from doctors; the Company’s various programs to stimulate Plenaxis purchases by physicians, such as delayed payment and rebate programs, were unsuccessful. ¶¶76-78, 97. This was because Plenaxis’ pricing structure offered physicians little opportunity to profit while at the same time it substantially increased the urologists’ risk of financial loss. ¶¶2, 52-55.

On December 6, 2004 the Company revealed that Q4 2004 sales would fall below Q3 sales and that Plenaxis faced many challenges as a result of problems with sales-force efficiency,

¹² Incorrectly asserting that Plaintiffs failed to allege this fact, Defendants suggest that the case evaporates because of it. Def. Mem. at 2. To the contrary, this partial disclosure of the truth, to wit, that revenue forecasts were overstated because the actual market for Plenaxis was far smaller than originally stated, causing the price to drop \$0.52 – 11.4% – from \$4.53 on May 21, 2004 (the last trading day before the disclosure) to a \$4.01 on May 26, 2004, after the market digested the news. Pastor Decl. at Ex. A (relevant prices of Praecis shares).

¹³ See, e.g., ¶¶75 (“work the gray areas”), 81-86, 87 (list of “niche” and “non-niche” terms), 88-90.

marketing efficacy, and continuing physician concerns over Medicare reimbursement. As a result, Praecis was withdrawing all guidance on Plenaxis sales and revenues and planned to later re-launch Plenaxis under a news sales model. ¶134. This statement shocked the market, causing damages to Praecis's shareholders when the Company's stock plummeted 25.8% in response. ¶135.

Instead of relaunching, in May, 2005, the Company fired 60% of its work force and suspended United States sales of Plenaxis to all but pre-existing users. ¶¶10, 136. More recently, Schering AG terminated its European licensing and distribution agreement with Praecis because of the limited scope of approval obtained in Germany, and Praecis was forced to sell its headquarters and R&D facility. Pastor Decl. at Exs. B and C (company press releases). Praecis shares currently trade at a mere \$0.66. *Id.* at Ex. A.

ARGUMENT

I. LEGAL STANDARD ON A MOTION TO DISMISS

It is only appropriate to dismiss an action where "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Roeder v. Alpha Indus., 814 F.2d 22, 25 (1st Cir. 1987) (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). In reviewing a motion to dismiss, the Court must "take all the plaintiff's allegations to be true and draw inferences in the plaintiff's favor." Aldridge v. A.T. Cross Corp., et al., 284 F. 3d 72, 78 (1st Cir. 2002) (district court erred by drawing its inferences in the defendants' favor). Moreover, "[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." Scheuer v. Rhodes, 416 U.S. 232, 236 (1974).

The Private Securities Litigation Reform Act of 1995 (the "PSLRA"), 15 U.S.C. § 78u-4, did not alter this standard of review, Aldridge, 284 F. 3d at 78, and was not intended to erect an insurmountable barrier to asserting a claim under the Exchange Act. As the First Circuit recently

stated in In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 199 (1st Cir. 2005):

We have previously stated that the PSLRA does not require the plaintiff to “plead evidence.” See In re Cabletron Systems, Inc., 311 F.3d at 33. As we understand, it was not Congress’s intention to bar all suits as to which the plaintiff could not yet prove a prima facie case at the time of the complaint, but rather to prevent suits based on a guess that fraud may be found, without reasonable basis or a clear understanding as to what the fraud consisted of, but in the hope of finding something in the course of discovery. Cf. In re Cabletron Systems, Inc., 311 F.3d at 30 (observing that the “statute was designed to erect barriers to frivolous strike suits, but not to make meritorious claims impossible to bring”)(emphasis added).

See also Florida State Bd. of Admin. v. Greentree Fin. Corp., 270 F.3d 645, 666 (8th Cir. 2001)

(“PSLRA does not license us to resolve disputed facts at this stage of the case”).

II. PLAINTIFFS HAVE SUFFICIENTLY ALLEGED MATERIALLY FALSE AND MISLEADING STATEMENTS

To state a claim under Section 10(b), a plaintiff must plead: (1) a misrepresentation or omission of a material fact; (2) scienter; (3) reliance on the misrepresentation; (4) damage resulting from the misrepresentation; and (5) loss causation. See e.g., Dura Pharmaceuticals, Inc. v. Broudo, 125 S. Ct. 1627, 1631 (2005); Stone & Webster, 414 F.3d at 193 (1st Cir. 2005).

The PSLRA requires plaintiffs to “specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading.” 15 U.S.C. §78u-4(b)(1). In this respect, the PSLRA is entirely consistent with First Circuit law and Fed.R.Civ.P. 9(b) which have long required plaintiffs to identify the false statements and explain why they are false.¹⁴ See Greebel v. FTP Software, Inc., 194 F.3d 185, 193-194 (1st Cir. 1999). The complaint herein amply satisfies the pleading requirements of the PSLRA.

A. The Complaint Satisfies the Pleading Standards of Rule 9(b) and the PSLRA

In addition to attempting to focus the Court’s attention on the statements in Def. Ex. A rather than the particularized allegations of the complaint, Defendants also contend that their false

¹⁴ Fed. R. Civ. P. 9(b) provides: “In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.”

statements are: non-actionable puffery or mismanagement claims, all forward-looking, and protected by the PSLRA's safe harbor. As explained below, Defendants' arguments are incorrect because not all of the alleged statements were forward looking, those that are were not issued with meaningful cautionary warnings and, the materiality inquiry requested is not suitable for a motion to dismiss.

1. Plaintiffs Have Adequately Plead That the Statements Were False When Made With The Requisite Particularity

Plaintiffs have more than satisfied the requirement that a securities fraud plaintiff "must allege with particularity the who, what, when, where, and why of each materially false or misleading misrepresentation or omission." Chalverus v. Pegasystems, Inc., 59 F. Supp. 2d 226, 232 (D. Mass. 1999). Plaintiffs allege multiple statements made by Praecis and Defendants Gefter, Heiden, and McLaughlin as well as SEC filing signed by Defendant English during the Class Period, including:

1. WHAT: "...we have estimated somewhere north of 15 to 20 to 30 percent of [the \$1.2 billion hormonal therapy market to treat prostate cancer] would be available to patients taking our drug." ¶109¹⁵;
WHO, WHEN, WHERE: Defendant Gefter, Chairman and Chief Executive Officer of Praecis; November 26, 2003; televised interview on CNBC;
WHY: Plenaxis' potential market was not the \$1.2 Billion hormonal therapy market, but a small portion thereof. Only 7.3% of prostate cancer patients experienced severe symptoms and Planaxis could only be sold to the subset of those patients who decide against surgical castration. As corroborated by a former Praecis oncology specialist (Confidential Source No. 3) and a former Praecis regional sales manager with over 20 years of experience in pharmaceutical sales (Confidential Source No. 7), due to

¹⁵ Defendant Heiden, the Company's President and Chief Operating Officer, made a substantially similar statement in a January 30, 2004 press release. ¶113.

its limited applicability, urologists would see no more than three patients a year that would qualify for Plenaxis. Confidential Source (CS) 7 reported that Plenaxis' developed market share (i.e., as opposed to its introductory year) was limited to \$10-20 million. ¶¶46-47.

2. WHAT: "The PLUS Program highlights that patient safety is our number one priority[.]..."

WHO, WHEN, WHERE: Defendant Heiden, Praecis's President and Chief Operating Officer; November 25, 2003; Press Release;

WHY: The Company insisted that sales personnel use unethical and possibly illegal methods to sell Plenaxis to patients that did not fit the drug's user profile ("off-indication"), thereby putting patients at serious risk. ¶¶29, 62, 75, 81-90.

3. WHAT: During 2004, the Company forecasts sales of Plenaxis to range from \$10.0 million to \$20.0 million.

WHO, WHEN, WHERE: Praecis; January 30, 2004, Press release;

WHY: This public forecast contradicted the Company's internal expectations. Based upon the number of expected patients and the number of vials they would use, even if all Plenaxis sales representatives achieved 100% of sales goals, yearly revenue would be less than half the low end of the Company's forecast ¶¶67-68.

4. WHAT: "Based upon the first quarter activity, the Company's prior Plenaxis (TM) sales forecast of \$10.0 million to \$20.0 million in revenue for 2004 remains unchanged" ¶120;

WHO, WHEN, WHERE: Defendant Heiden; April 30, 2004; Press release;

WHY: By April 2004, Plenaxis stocking orders and sales were substantially below

expectations, Praecis's "delayed payment" program was unsuccessful, significant returns of Plenaxis from physicians existed, 100% success of internal sales quotas would equate to only half the Company's low revenue projection; and physicians complained about side-effects and exam room tie-ups. ¶¶67-70, 76-79.

5. WHAT: "... this experienced [Plenaxis sales] team is now calling on physicians to educate and build product awareness..."¹⁶

WHO, WHEN, WHERE: Defendant Heiden; May 24, 2004; Press release;

WHY: By then, the Company began to experience voluntary terminations by its experienced sales staff. ¶122. The sales training received to "educate" physicians was, in reality, an unethical attempt to downplay the serious risks of prescribing Plenaxis in order to expand the drug's limited market. ¶62.

6. WHAT: We have seen evidence of the success of this strategy in a trend of increasing weekly sales which began in the latter portion of the second quarter.

WHO, WHEN, WHERE: Defendant Heiden; July 30, 2004; Press release;

WHY: By then, the Company product returns, lack of sales, and physician rejection of Plenaxis. ¶¶4, 69, 76-78, 122.

7. WHAT: We are encouraged by the growing base of sales to repeat prescribers. This trend suggests that following their first experience with Plenaxis(R), physicians are pleased with the results and thus are continuing to treat existing patients..."

WHO, WHEN, WHERE: Defendant McLaughlin; October 26, 2004; Press release;

WHY: Plenaxis sales were substantially below expectations, Praecis "delayed payment" program was unsuccessful, significant returns of Plenaxis from physicians

¹⁶ A substantially similar statement was made in Praecis's July 30, 2004, press release., ¶127, following the sales meeting where representatives were instructed to sell off-label, spurring additional defections. ¶¶81-90.

existed, Praecis's pricing structure offered urologists little opportunity to profit unlike competing medications, and the Company's experienced sales staff was being replaced with amateurs. Moreover, unlike Plenaxis, Lupron, used for the past 15 years did not contain a "black box" warning label identifying significant risks in prescribing the drug which increased malpractice concerns. ¶¶ 3-4, 50, 76-78, 91.

2. Plaintiffs' Allegations Of False And Misleading Statements Are Material.

"A fact is material if it is substantially likely that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available. Information which would have assumed actual significance in the deliberations of a reasonable shareholder is material." Basic v. Levinson, 485 U.S. 224, 231-232 (1988). The issue of materiality is best left to the trier of fact. Id. See Lucia v. Prospect St. High Income Portfolio, Inc., 36 F.3d 170, 176 (1st Cir.1994); Scritchfield v. Paolo, 274 F. Supp. 2d 163, 170 (D.R.I. 2003). Thus, "we review the complaint only to determine that it pleads the existence of such statements and presents a plausible jury question of materiality." In re Cabletron Sys. Inc., 311 F.3d 11, 34 (1st Cir. 2002) (emphasis added). Dismissal at the pleading stage is only appropriate in those rare instances in which the statement or omission is so immaterial that reasonable minds could not differ. Cooperman v. Individual, Inc., 171 F.3d 43, 49 (1st Cir. 1999).

Throughout the Class Period, Plaintiffs allege that Defendants misstated and failed to disclose critical information concerning Praecis's only marketable product, Plenaxis. A reasonable investor would not have purchased Praecis stock at the artificially elevated Class Period prices if Defendants had revealed that their only product, Plenaxis, was not being accepted by physicians, that sales forecasts could only be met by selling Plenaxis off-label, that much of the sales force left, and

that Plenaxis revenue projections were inconsistent with Defendants' internal sales forecasts. Indeed, when Defendants partially disclosed the truth, by withdrawing 2004 guidance on May 24, 2004, the stock price declined by more than 10% immediately thereafter. Again, on December 6, 2004, when all numerical guidance was withdrawn and the sales efforts touted in earlier press releases were suspended, Praecis's price dropped a whopping 35.8%. ¶135. The misstatements' materiality is thus shown by the market's reaction to negative news about Plenaxis. See In re Campbell Soup Co. Sec. Litig., 145 F. Supp.2d 574, 589 (D.N.J. 2001)("[I]n an efficient market, significant change in a stock's price may be determinative of whether a statement...was material."); City of Monroe Employees Retirement Sys. v. Bridgestone Corp., 399 F.3d 651, 676 (6th Cir. 2005).

In Ex. A and throughout their brief, Defendants improperly recast Plaintiffs' allegations, choosing either statements not identified by Plaintiffs as false and misleading, or discussing only parts of the statements alleged. This they cannot do. See In re Terayon Comms. Systems, Inc., No. C 00-01967 MHP, 2002 WL 989480, at *3 (N.D. Cal. Mar. 29, 2002) (chastising defendants for mischaracterizing complaint). Consequently, their use of the buzz words "puffery" and "general optimism" should fall on deaf ears.¹⁷

3. Plaintiffs' Allegations Of False And Misleading Statements Are More Than Non-Actionable Mismanagement

¹⁷ Contrary to Defendants' contention, Praecis's statements were not simply "classic examples of non-actionable corporate puffery." Orton v. Parametric Tech. Corp., 344 F.Supp.2d 300, 301 (D. Mass. 2004); See Def. Mem at 8. In Orton, the District Court found the phrase "we are pleased with the performance" one which no reasonable person could rely. Id. In contrast, Defendants herein did not simply claim they were "pleased" with the Company's performance. Rather, Defendants explicitly claimed that the Company was capitalizing on the Plenaxis commercial opportunity and that customers were accepting Plenaxis although Defendants knew they were not seeing strong demand for Plenaxis or significant repeat business from their existing customers and in fact knew their existing customers were returning Plenaxis. ¶122. Equally unavailing is Defendants' citation to Peritus Software Servs., Inc. Sec. Litig., 52 F. Supp. 2d 211, 219-20 (D. Mass 2000), where defendants successfully argued that the phrase "unprecedented market demand for [its] products," which was made at the initial launch of the company's product, was "mere corporate puffery." Id. In stark contrast, several months **after** the initial launch of Plenaxis, Defendants claimed revenue projections of 10-20 Million were on target despite poor sales, product returns, and a dwindling sales force.

Defendants' erroneously contend that the facts supporting the mispricing of Plenaxis, lack of a necessary distribution system, deteriorating sales force morale (and increasing departures) and the attempts to sell the drug "off label" are nothing more than non-actionable mismanagement. Def. Mem. at 21-22. To the contrary, those allegations set forth the facts necessary to demonstrate that Company statements were materially false and misleading because those facts undermined any revenue projections and were directly contrary to contemporaneous statements being made by the Defendants of the Company's then-existing ability to sell Plenaxis.

Moreover Defendants misstate the law. By enacting §10(b), Congress "did not intend to regulate transactions which constitute no more than mere corporate mismanagement." Sante Fe Industries, Inc. v. Green, 430 U.S. 462, 479 (1977). Where, as here, however, a claim concerning mismanagement is accompanied by deception, misrepresentation or nondisclosure of material facts, that claim is actionable. In re Sirrom Capital Corp. Sec. Litig., 84 F. Supp. 2d 933, 941 (M.D. Tenn. 1999)(citing Sante Fe, 430 U.S. at 476); see also In re Home Health Corp. Sec. Litig., 1999 WL 79057, at *13 (E.D. Pa. Jan. 29, 1999); Gross v. Medaphis, 977 F. Supp. 1463, 1473 (N.D. Ga. 1997). Whereas Plaintiffs have challenged misstatements and concealment of the truth regarding Plenaxis revenue projections, sales and marketing efforts and messages, and the financial and malpractice concerns voiced by physicians, the CAC states actionable claims against Defendants.

4. **The PSLRA's Safe Harbor Provides A Limited Exception Not Intended To Swallow The 69-Year Old Rule That Material Misrepresentations Made With Scienter, Give Rise To Liability For Securities Fraud**

Unable to avoid Plaintiffs' factual allegations that they had materially mislead the market regarding Plenaxis' potential market, the Company's salesforce and doctors' acceptance of the drug, Defendants attempt to jam the square pegs into round holes and recharacterize most the

alleged false and misleading statements as forward-looking in a desperate attempt to fall under the PSLRA's safe harbor provision. Rather, it is abundantly clear that Defendants misrepresented the current state of affairs at the time most of the statements were made and the safe harbor provisions do not apply.¹⁸

a. Most of Defendants' False and Misleading Statements Are Statements Of Current Fact

It is uncontroverted that statements that are not forward-looking are not protected by the safe harbor. In *re Stone & Webster, Inc., Securities Litigation*, 414 F.3d 187, 213 (D. Mass. 2003) (the safe harbor of the PSLRA does not confer a carte blanche to lie in such representations of current fact). So, for example, the alleged false and misleading statement by Defendants in the Company's July 30, 2004 press release that "All of the field force has been hired, trained and is now calling on physicians." is a statement of current fact and thus not protected by the Safe Harbor.¹⁹ That same press release also references "current efforts" and present "trends" concerning Plenaxis sales which can be ascertained to either true or false when made. ¶¶110, 115, 122, 125.²⁰ *Bryant v. Avado Brands, Inc.*, 100 F. Supp. 2d 1368, 1382 (M.D. Ga. 2000), reversed on other grounds, *Bryant v. Dupree*, 252 F.3d 1161 (11th Cir. 2001)(whether plan is "on track" is "capable of being assessed for falsity in the present).²¹

¹⁸ To the degree portions of certain misleading statements were forward-looking, those portions did not meet the requirement of the PSLRA safe harbor, as briefed below.

¹⁹ As previously noted, Defendants made a similar false statement of present fact in the Company's May 24, 2005 press release: "this experienced [Planaxis sales] team is now calling on physicians. In fact, at the time of this press release, the Company was experiencing mass voluntary terminations by its experienced sales staff." ¶125.

²⁰ Defendants October 26, 2004 press release contains similar statements of current "trends".

²¹ Other non-forward-looking statements that are alleged to be false and misleading include: (a) Geffer's statements in the Company's April 30, 2004 press release that "During the first quarter of 2004, Praecis continued to capitalize on the Plenaxis commercial opportunity;" and "We have seen evidence of the success of this strategy in a trend of increasing weekly sales which began in the latter portion of the second quarter;" (b) McLaughlin's statement in Praecis's October 26, 2004 press release: "We are encouraged by the growing base of sales to repeat prescribers. This trend suggests that following their first experience with Plenaxis(R), physicians are pleased with the results and thus

The ability to currently evaluate such statements is evidenced by the statements that “Praecis continued to capitalize on the Plenaxis(TM) commercial opportunity,” and “we are encouraged by the feedback from physicians and expect to build sales during the second half of the year as awareness of the product grows...” ¶¶121. These statements are not forward looking as they misrepresented the then current state of affairs at Praecis: (1) Plenaxis was not capitalizing on the commercial opportunity as doctors were rejecting and returning the drug; (2) the salesforce was revolting and leaving in droves; and (3) the Company’s only plans to increase sales were unethical and illegal methods. ¶¶122.

Defendants erroneously categorize current financial and market statements as forward looking. Plaintiffs allege that Defendants materially overstated the *existing* market for Plenaxis at \$180 to \$360 million. ¶¶108, 109.²² In reality, because Plenaxis could only be legally sold to the subset of prostate cancer patients with severe symptoms, who refused castration, and has a treating physician enrolled in the PLUS program, the potential developed market for Plenaxis was far lower, only \$10-20 million per year. While investors may have known that Plenaxis might not capture its entire market, these statements misled investors as to the potential upside for Plenaxis. Defendants incorrectly characterize these statements as forward-looking “revenue and market projections” Def. Mem. at 11. See Stone & Webster, 414 F.3d at 213 (statement not within the safe harbor if the allegation of falsehood relates to non-forward-looking aspects of the

are continuing to treat existing patients...” The fact that defendants added the words “we are encouraged” to an affirmative representation of a “growing base” does not immunize the statement. See In re Oxford Health Plans, Inc., 187 F.R.D. 133, 141 (S.D.N.Y. 1999)(prefatory “[we] believe” does not immunize false statement).

²² “We’ve talked about a 15% plus revenue opportunity of the current \$1.2 billion market,” and “we have estimated somewhere north of 15 to 20 to 30 percent of that size market would be available to patients taking our drug.” ¶¶108, 109. Furthermore, the statements made during defendant Gefter’s CNBC appearance were not identified as forward looking and were not accompanied by *any* cautionary language.

statement); see also Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1213 (1st Cir. 1996).²³

Defendants also miscategorize several statements as forward looking by labeling them “goals and plans for the future” Def. Mem. at 11. Plaintiffs allege that Defendants touted the safety of the PLUS Program and that they would sell Plenaxis to patients “who have limited or no other treatment options available.” ¶¶106, 107. These statements were contrary to management’s instruction²⁴ that sales personnel should employ unethical and illegal methods to sell the drug to patients who did not need the drug and had other alternatives, thereby endangering their health.

b. None of Defendants Statements Qualify for the PSLRA Safe Harbor At the Motion to Dismiss Stage

Under the PSLRA, the “statutory safe harbor forecloses liability if a forward-looking statement ‘is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement’” Asher v. Baxter Int’l Inc., 377 F.3d 727, 729 (7th Cir. 2004)(quoting 15 U.S.C. § 77z-2(c)(1)(A)(I)).” However, as Judge Easterbrook found, because the language of safe harbor is so malleable, it is unsuitable on a motion to dismiss:

The fundamental problem is that the statutory requirement of “meaningful cautionary statements” is not itself meaningful. What must the firm say? Unless it is possible to give a concrete and reliable answer, the harbor is not “safe”; yet a

²³ For example, Heiden’s statement in the Company’s April 30, 2004 that “Based upon the first quarter activity, the Company’s prior Plenaxis sales forecast of \$10.0 million to \$20.0 million in revenue for 2004 remains unchanged,” is a statement of current business conditions and therefore not a forward-looking statement. By making the statement, Defendants are representing that a reasonable person who knew what Defendants knew at the time the statement was made could reasonably conclude that Praecis was likely to meet its revenue goals. In re Vivendi Universal, S.A., 2004 WL 876050 *7 (S.D.N.Y. 2004) (company’s expressed confidence that it was “on track” to achieve earnings targets was actionable); In re Secure Computing Corp. Securities Litigation, 120 F.Supp.2d 810, 818 (N.D. Cal. 2000) (statements that company was on track to meet analysts’ earnings expectations not forward looking.)

²⁴ In addition to teaching sales techniques to stress a broader use, former employees recounted that that management did not address their complaints the suggested use of improper sales tactics.

word such as “meaningful” resists a concrete rendition and thus makes administration of the safe harbor difficult if not impossible. It rules out a caution such as: “This is a forward-looking statement: caveat emptor.” But it does not rule in any particular caution, which always may be challenged as not sufficiently “meaningful” or not pinning down the “important factors that could cause actual results to differ materially”--for if it had identified all of those factors, it would not be possible to describe the forward-looking statement itself as materially misleading. A safe harbor matters only when the firm’s disclosures (including the accompanying cautionary statements) are false or misleadingly incomplete; yet whenever that condition is satisfied, one can complain that the cautionary statement must have been inadequate. The safe harbor loses its function. Yet it would be unsound to read the statute so that the safe harbor never works; then one might as well treat § 77z-2 and § 78u-5 as defunct.

Asher, 377 F.3d at 729.

Indeed, the difficulty in assessing the meaning of “meaningful” lead Judge Easterbrook to conclude:

The problem is not that what actually happened went unmentioned; issuers need not anticipate all sources of deviations from expectations. Rather, the problem is that there is no reason (on this record) to conclude that Baxter mentioned those sources of variance that (at the time of the projection) were the principal or important risks. . . . Moreover, the cautionary language remained fixed even as the risks changed. . . . This raises the possibility--no greater confidence is possible before discovery--that Baxter omitted important variables from the cautionary language and so made projections more certain than its internal estimates at the time warranted. Thus this complaint could not be dismissed under the safe harbor, though we cannot exclude the possibility that if after discovery Baxter establishes that the cautions did reveal what were, ex ante, the major risks, the safe harbor may yet carry the day.

Id. at 735; see also Selbst v. McDonald’s Corp., 2005 U.S. Dist. LEXIS 23093, 54-56 (D. Ill.

2005)(issue of “meaningful warning” one of fact, not suitable to a motion to dismiss); In re

Lucent Techs., Inc. Sec. Litig., 217 F.Supp.2d 529, 557 (D.N.J. 2002)(same); In re Prison Realty

Sec. Lit., 117 F. Supp. 2d 681, 690 (M.D. Tenn. 2000)(same).

Here, as in Asher, there is “no reason (on this record) to conclude” that Praecis mentioned the sources of variance that at the time of the projections “were the principal or important risks.” In particular, the cautionary language cited by Defendants (Def. Mem. at 14-16) is general and

unspecific, nowhere indicating any discrepancy between Praecis's revenue projections and current data relating to the marketability of Plenaxis as well as current sales data. In re Transkaryotic Therapies, Inc. Sec. Litig., 319 F.Supp.2d 152, 161 (D. Mass.2004) (to fall within the PSLRA's safe harbor, a statement must be accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially)

i. November 26, 2003 Conference Call

Statements made during the course of conference calls, are only covered by the safe harbor if defendants: (1) identify the statement as forward looking; (2) inform listeners that actual results might differ from those projected; (3) inform listeners that additional information concerning the factors that could cause actual results to differ can be found in a readily available written document; (4) identify the document or portion thereof where the information can be found; and if (5) the information in the written document is satisfactory meaningful cautionary language. 15 U.S.C. §78u-5(c)(2)(A)&(B). Defendant Gefters's generalized warning at the outset of the conference call, which did not warn that Plenaxis revenue projections contradicted existing facts concerning the marketability of Plenaxis, failed to comply with the PSLRA:

"Before getting started I want to remind everyone that - about our news release and Webcast contain forward-looking statements, and these statements are subject to numerous factors and uncertainties. And please refer to the factors set forth in our news release as well as the risks set forth from time to time in our filings with the SEC."

Def. App., Ex. 2 at 1. This legally deficient warning fails to satisfy three of the required elements for safe harbor protection. Failure to satisfy just one prong disqualifies. See, e.g., In re Champion Enterprises, Inc. Sec. Litig., 144 F. Supp. 2d 848, 865 (E.D. Mich. 2001)(failure to warn factors could "cause actual results to materially differ"). Defendants' general warning statement, referencing unspecified SEC filings, did not provide particular factors such as the

projected earnings of Plenaxis may be inconsistent with known currently available data.

Moreover, Defendants' warning statement is further deficient because it failed to identify "which statements were forward-looking statements and which were not." In re ATI Techs., Inc., Sec. Litig., 216 F.Supp.2d 418, 443 n.18 (E.D. Pa. 2002).²⁵

ii. November 26, 2003 CNBC Interview

While Plaintiffs do not concede that the statements made by Defendant Gefter during the CNBC interview were forward-looking, they were not identified as such and not accompanied by **any** cautionary language whatsoever. Defendants concede this point, albeit fleetingly, in a footnote. Def. Mem. at 12 n. 8.

iii. 2004 Press Releases and SEC Filings

Defendants broadly drafted warning contained in their press releases that statements concerning Plenaxis are based on current beliefs and expectations as to future outcomes and are subject to numerous factors and uncertainties, does not adequately caution investors to specific concealed risks regarding then-existing information that directly contradicted Defendants' statements. See In re Sepracor, Inc. Sec. Litig., 308 F.Supp.2d 20, 34 (D. Mass. 2004)("Vague or boilerplate disclaimers are insufficient to invoke safe harbor protection.")

Other cautionary statements in Preacis' SEC filings regarding FDA limitations and market acceptance simply recited the variables affecting the business of any company trying to sell a new product subject to FDA approval. See Yanek v. Staar Surgical Co., No. CV 04-8007 SJO, 2005 WL 2304156 (C.D. Cal. Sept. 19, 2005)(so holding). To be meaningful within the PSLRA, cautionary language would have had to warn investors of the existing problems and

²⁵ Defendants' reliance on In re Parametric Tech. Corp. Sec. Litig., 300 F. Supp. 2d 206, 219 (D. Mass. 2001) is misplaced. Parametric warning during the conference call referenced various SEC filings which identified a number of particular factors that might have an adverse affect on the actual results of operations.

specific facts then known to be plaguing Plenaxis. Defendants did not make such disclosures because they would have undermined shareholder confidence in both the company's management and Plenaxis.²⁶

Furthermore, it is misleading to present a risk as merely a contingency after the risk has materialized. In re Convergent Techs. Sec. Litig., 948 F.2d at 515; see also Huddleston v. Herman & MacLean, 640 F.2d 534, 544 (5th Cir. 1981) ("To warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit."). Thus, general statements of potential risks which conceal specific existing problems are actionable. Rubinstein v. Collins, 20 F.3d 160, 171 (5th Cir. 1994); Mayer v. Mylod, 988 F.2d 635, 639 (6th Cir. 1993); In re Prudential Sec. Ltd. Pshps. Litig., 930 F. Supp. 68, 74 (S.D.N.Y. 1996) ("Warnings of possible detriment are insufficient if they are simply a smoke screen to cover a company's internal reasonably informed certainty of detriment.").

Here, when the Company issued its forecasts in January and April 2004, Defendants never warned or cautioned investors that: (i) currently existing statistical data indicated that only a small market existed for Plenaxis; (ii) the need to create a distribution network would cause the Company to incur substantial costs and slow the marketing of Plenaxis; (iii) the pricing structure, 30-minute wait period, and increased malpractice risk created a strong economic disincentive for urologists.; and (iv) Defendants planned to rely on off-label sales to meet sales goals. These risks made optimistic revenue projections within the time frame indicated by Defendants in their

²⁶ See Geabhardt v. Con Agra foods, Inc., 335 F.3d 824, 829-830 (8th Cir. 2003)(omitted information was material because a reasonable investor would be interested in knowing that, at worst, the senior managers of ConAgra were in league with the deceptive management of UAP or, at best, were oblivious to their underlings' malfeasance. Management's integrity would probably be important to investors)

public statements impossible. Moreover, as Defendants admit (Def. Mem. at 14-16), despite desperately deteriorating conditions (*i.e.* the change in the pricing structure, the rejection of Plenaxis by urologists, the departure of trained and experienced sales representatives and significant returns of Plenaxis by doctors), Praecis never changed its risk disclosures. Asher, 377 F.3d at 734-35 (where cautionary language “remained fixed even as the risks changed” raises the possibility that the defendant “omitted important variables from the cautionary language and so made projections more certain than its internal estimates at the time warranted.”)

d. Defendants’ Statements were False When Made

Aside from the provision of inadequate risk warnings, if a corporation makes certain identified projections regarding financial performance or plans for future operations, see 15 U.S.C. §78u-5(i)(A)-(F), liability will attach if plaintiffs can prove that the statement was made with actual knowledge that it was false or misleading. §78u-5(c)(1)(B). In short, the safe harbor does not protect forward-looking statements that are known by the defendant to be false when made. See In re Priceline.Com Inc. Sec. Litig., 342 F. Supp. 2d 33, 49 (D. Conn. 2004); In re Alliance Pharm. Corp Sec. Litig., 279 F. Supp. 2d 171, 192 (S.D.N.Y. 2003) (stating that the PSLRA does not protect the defendant when the statement was knowingly false when made); In re Landry’s Seafood Rest., Inc., 2001 WL 34115784, at *20 (S.D. Tex. 2001).²⁷

Thus, even if this Court determines that Praecis’s forecasts are forward-looking and

²⁷ Defendants disagree, citing Harris v. Ivax Corp., 182 F.3d 799, 806 (11th Cir. 1999) for the proposition that a finding that meaningful warning was given terminates further inquiry, thus providing shelter for knowingly false statements. Def. Mem. at 13. Other courts have held that a claim is stated if a forward looking statement was alleged to have been made with actual knowledge that it was false and misleading, even if it was accompanied by meaningful risk warnings. No. 84 Employer- Teamster Joint Council Pension Trust Fund v. America West Holding Corp., 320 F.3d 920, 936, 937 n.15 (9th Cir. 2003); In re Lucent Techs., Inc. Sec. Litig., 217 F. Supp. 2d 529, 557 (D.N.J. 2002)(so holding). One court which followed Ivax nevertheless indicated that where the defendant knowingly lies only the warning “we may be lying” may be the only meaningful warning. See In re Seebeyond Techs. Corp. Sec. Litig., 266 F. Supp. 2d 1150 (C.D. Cal. 2003)(“If the forward-looking statement is made with actual knowledge that it is false or misleading, the accompanying cautionary language can only be meaningful if it either states the belief of the speaker that it is false or misleading or, at the very least, clearly articulates the reasons why it is false or misleading.”)

covered by risk warnings, they may still be actionable if the speaker does not genuinely or reasonably believe them or is aware of undisclosed contradictory facts. In re IBM Corp. Sec. Litig., 163 F.3d 102, 107 (2d Cir.1998) (citations omitted).²⁸ Defendants may be held liable for their Plenaxis revenue projections because at the time they were made Defendants were aware of facts which undermined the projections and therefore made the projections materially misleading. See Dunn v. Borta, 369 F.3d 421, 431 (4th Cir. 2004) (assertion that the projections lacked a reasonable basis).²⁹

Defendants are presumed to know facts critical to the Company's operations. Guerra v. Teradyne Inc., 2004 WL 1467065 *27 (D.Mass. Jan 16, 2004). Since Plenaxis was Praecis's only product commercially available, and thus the Company's only source of revenue, Defendants are presumed aware of critical facts concerning Planaxis. See In re Amylin Pharmaceuticals, Inc. Sec. Litig., No. 01CV1455BTM 2002 WL 31520051, at *8 (S.D. Cal. Oct. 10, 2002)(so holding). Specifically, at the time Defendants were touting optimistic Plenaxis revenue projections, they knew of the drug's severe marketing limitations (¶ 2) and that the

²⁸ In In re ValuJet, Inc. Sec. Lit., 984 F. Supp. 1472, 1479 (N.D. Ga. 1997), the airline's statement of aggressive planned expansion, clearly forward looking on its face, was not entitled to safe harbor protection because the airline did not disclose that as a result of a failed inspection by the FAA, the FAA's express approval would be required before any new planes could be purchased and any new routes added. Similarly, in In re Cell Pathways, Inc., No. 99-275, 2000 WL 805221 (E.D. Pa. June 20, 2000), the defendant's statement that its experimental drug "shows promise for cancer therapy," although forward looking on its face, was actionable because at the time it was made, the defendant company knew of serious flaws in its trials testing the drug's efficacy. Rejecting application of both the "bespeaks caution" doctrine and the safe harbor to the defendant's "language of futurity," the court held that the PSLRA was not enacted to "permit companies to completely avoid liability for omissions of existing material facts by simply manipulating verb tense." Id. at * 11 & n. 13

²⁹ Defendants assert that under the PSLRA's safe harbor provision Plaintiffs must plead that the Defendants had "actual knowledge" and have failed to do so. Defendants are wrong. Here, plaintiffs have reported multiple sources directly contradicting the revenue projections, including, but not limited to, the AUA study, the statements of Confidential Sources directly to Defendants, the frequent sales meetings and, the Spider system. ¶¶ 35, 46-47, 74, 100-104. "[C]ourts have found that plaintiffs have sufficiently alleged actual knowledge, where the complaint contains allegations that defendants were high level managers, who had access to frequent reports which would lead a reasonable person to believe that the predictions being made in public statements are not accurate and/or missing relevant information." Asher v. Baxter Int'l, Inc., 2005 U.S. Dist. LEXIS 2131, at *19-*20 (N.D. Ill. February 3, 2005) (Citing In re Globalstar Secs. Litig., 2003 U.S. Dist. LEXIS 22496, 2003 WL 22953163, at *8 (S.D.N.Y. Dec. 15, 2003); In re Compuware Secs. Litig., 301 F. Supp. 2d 672, 682 (E.D. Mich. 2004)).

AUA found that Planaxis could only be prescribed to a small subset of the approximately 7.3% of total prostate cancer patients. ¶46. While Plaintiffs do not concede the November 2003 market-size statements were forward-looking, based on the small number of potential patients that could take the drug, Defendants had no reasonable basis to publically represent that the Planaxis market consisted of 15-30% of a \$1.2 billion market or to predicate the 2004 revenue forecast of \$10-20 million upon this figure.

Further evidence that Defendants had no reasonable basis to believe their revenue projections is that they dwarfed the Company's own sales quotas which ideally could only result in revenues equaling about half the low-end revenue projections. ¶¶ 67-68. Moreover the Company's own unethical policy in pressuring their sales team to sell Planaxis off indication and downplay the potential side-effects in a desperate attempt to boost sales further demonstrates their knowledge that they could not meet revenue projections. ¶¶81-90. This fact is confirmed by Confidential Witnesses Nos. 2, 3, and 5 who are all former Planaxis sales representatives for Praecis. *Id.*

While Plaintiffs do not concede that statements relating to Planaxis sales were forward-looking, to wit, statements in the middle of the Class Period regarding the Company's experienced and trained sales staff, were clearly false when made as Praecis was experiencing significant attrition of its sales staff and was subsequently hiring inexperienced sales representatives. ¶¶91,122. This fact is confirmed by Confidential Witness No. 1 who was a former salesperson for Praecis.

B. Confidential Witnesses Have Been Pled with Sufficient Particularity

Defendants argue that facts attributable to the confidential sources (CS) referenced in the CAC are too conclusory. Def. Mem. at 20-24. Defendants are wrong. The CS allegations in the

CAC have been pled with enough specificity so that information provided by these witnesses may be deemed credible and reliable.

It is well accepted that allegations in a complaint are more reliable and credible when based on information from corroborating sources. Bourjaily v. U.S., 483 U.S. 171, 179-80 (1987). It is equally well settled that securities fraud plaintiffs may rely on confidential sources without specifically naming them “provided they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.” In re Cabletron Sys., Inc., 311 F.3d 11, 29 (1st Cir. 2002)(quoting Novak v. Kasaks, 216 F.3d 300, 314 (2d Cir. 2000)). Plaintiffs are not required to plead exact job titles, describe the sources’ responsibilities and duties in detail or allege access to specific company documents. In re Atlas Air Worldwide Holdings, Inc. Securities Litigation, 324 F.Supp.2d 474, 493 (S.D.N.Y. 2004). Exact dates of employment need not be included, as they “would significantly erode the confidentiality of these sources.” In re SeeBeyond Technologies Corp. Securities Litigation, 266 F.Supp.2d 1150, 1159 (C.D. Cal. 2003). In addition, the court should view the statements of plaintiffs’ confidential sources as a whole. In re Atlas Air Worldwide Holdings, 324 F.Supp.2d. at 493.

CS 1-6 were all Plenaxis sales representatives during the Class Period with CS 1 and 2 having 20 and 15 years experience in pharmaceutical sales respectively. ¶¶ 28-33. Their testimony as to the extremely limited market for Plenaxis at the time Defendants were making false and misleading statements regarding the drug’s market potential, is based on their extensive experience within the pharmaceutical industry. As Plenaxis sales representatives, these CSs have first hand knowledge concerning: 1) physicians’ reluctance in prescribing the drug; 2) management’s directive to increase sales by illegally expanding the patient base beyond FDA

limitations; 3) dwindling sales and substantial returns of Plenaxis; and 4) the substantial attrition among the sales staff which contradicted Defendants' statements that the Company's 40 person experienced sales team was calling on physicians. Additionally, CS 1 informed management that the pricing structure for Plenaxis was significantly flawed in that it did not provide a significant enough profit motive for the urologists to prescribe the drug. ¶¶ 53-54. Contrary to Defendants' assertion, these CSs have credible knowledge of contemporaneous facts that Defendants' knew at the time of their alleged false and misleading statements. Thus, Defendants' bald assertion that the CS's testimony is conclusory is meritless.

CS 7 was a Praecis Regional Sales Manager with over 20 years experience in pharmaceutical sales and based on her considerable experience, confirms the fact that Plenaxis' market potential was severely limited despite Defendants' representations to the contrary. ¶ 34. In fact, during CS 7's employment interview with a senior Praecis manager, CS 7 mentioned that the overall market potential for Plenaxis was at best \$10-\$20 Million. ¶ 47. CS 7's well qualified opinion stands in stark contrast to Defendants' public statements that estimated first year revenues from Plenaxis to be \$10-\$20 Million. As a Regional Sales Manager, CS 7 would certainly have direct knowledge of the dismal Plenaxis sales and significant returns, as well as the various failed sales incentives. ¶ 79, 97-98.

As a Praecis staff accountant during the Class Period, CS 8 certainly had direct knowledge relating to the weak sales of Plenaxis and, in fact, stated that orders from distributors were infrequent. ¶¶ 35, 70. Most importantly is the fact that during the Class Period, CS 8 provided information directly to Defendants regarding Plenaxis poor sales performance. The allegations attributed to the CSs, when taken together, provide corroborating details of the inconsistent contemporaneous statements made by Defendants.

III. PLAINTIFFS ADEQUATELY PLEAD SCIENTER.

Scienter is defined as a mental state embracing intent to deceive, manipulate or defraud. Aaron v. SEC, 446 U.S. 680 (1980); see also Ernst & Ernst v. Hochfelder, 425 U.S. 195, 193 n.12 (1976). Section 21(D)(b)(2) of the PSLRA requires that a plaintiff state “with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2). The standard for pleading scienter in this Circuit is clear. In order to plead a “strong inference” of scienter, plaintiffs must plead defendants’ knowledge or recklessness. Greebel v. FTP Software, Inc., 194 F.3d at 198-201. Moreover, the PSLRA does “not mandate a particular test to determine scienter, “ instead the court must analyze the particular facts of each individual case. Aldridge, 184 F.3d at 82 (citing Greebel 194 F.3d at 196). Accordingly, as the First Circuit stated in Aldridge:

[T]he plaintiff may combine various facts and circumstances indicating fraudulent intent to show a strong inference of scienter. As part of the mix of facts, the plaintiff may allege that the defendants had the motive (“concrete benefits that could be realized by the false statements and wrongful nondisclosures”) and opportunity (“the means and likely prospect of achieving concrete benefits by the means alleged”) to commit the fraud.

Id.

Indeed, “[s]cienter may be demonstrated by indirect evidence and may extend to a form of extreme recklessness that ‘is closer to a lesser form of intent.’” Cabletron, 311 F.3d at 39 (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 198-99 (1st Cir. 1999)). Moreover, plaintiffs need not prove up their allegations at the pleading stage or to allege more than can reasonably be expected at the pleading stage when all discovery is stayed. See Cooperman v.

Individual Inc., 171 F.3d 43, 48-49 (1st Cir. 1999) (“We cannot hold plaintiffs to a standard that would effectively require them, pre-discovery, to plead evidence.”).

Plaintiffs’ allegations, taken as a whole, satisfy this Circuit’s scienter pleading requirements. These allegations include the facts that:

- **Defendants concealed that Plenaxis was largely being rejected by physicians.**

Defendants knew Praecis’s only product, Plenaxis, was not being well-received by physicians, based not only on direct contact with the sales staff, but through the Company’s internal network called SPIDER. ¶¶ 100-102, 142. Through SPIDER, Defendants could track sales by week or month as well as chart individual sales performance. ¶¶ 100-102. In addition, Defendants participated in weekly conference calls with sales staff and evaluations based on those meetings were submitted to management. ¶¶ 102-104. As a result, Defendants were keenly aware of the significant rejection of Plenaxis by its target market resulting in lackluster sales, with many sales being returned. ¶¶ 100-102, 142. Also, various programs to entice sales including a “delayed payment” and credits earned with purchase program, were failures. ¶¶ 76-79.

Further, the Company’s experienced sales staff were voluntarily leaving en mass due, in part, on the Company’s insistence that sales personnel use unethical and possibly illegal methods to sell Plenaxis to patients that did not fit the drug’s user profile (“off-indication”). ¶¶ 81-96. In fact, as confirmed by Confidential Source No. 5 (CS 5), who was then a Plenaxis sales representative, Defendant Heiden was directly made aware of these problems during the Class Period through a letter he reviewed from CW5.³⁰ ¶¶ 73-74. In addition, Defendants Heiden, Gefter, and McLaughlin were all present at a national sales conference held at the Hyatt Regency

³⁰ According to CW5, Heiden contacted CW5 to discuss the letter, and revealed that the Praecis Board of Directors also reviewed the letter. ¶74.

in Cambridge, Massachusetts held on June 21-23, 2004, at which time the Individual Defendants actively pursued the off-indication strategy. ¶¶ 83-85, 89. This fact is confirmed by Confidential Witnesses Nos. 2, 5, 6 who attended the conference. ¶¶ 83-85. Defendants' willingness to endanger the lives of cancer patients in a desperate attempt to increase revenue for Praecis clearly demonstrates scienter.

• **Defendants knew their sales projections had no basis in fact**

At the time the FDA approved Plenaxis for sale on November 25, 2003, Defendants were aware that the FDA narrowly defined the types of patients to whom Plenaxis could be prescribed, based, in part, on the approval studies demonstrating that Plenaxis users were at risk of life-threatening allergic reactions. ¶¶ 2, 42. Accordingly, Plenaxis could be prescribed only to those patients with severe symptoms and who refused surgical castration which the FDA estimated to be, at best, 5-10% of prostate cancer patients. ¶¶ 2, 46. The FDA's estimate is consistent with a 2002 study by the American Urologic Association which found that only 7.3% of prostate cancer patients had severe symptoms. ¶ 46. Of course, patients eligible for Plenaxis would be comprised of only a subset of this 7.3% since, in addition to severe symptoms, patients would also have to refuse surgical castration **and** their doctors enrolled in the Plenaxis risk management program approved by the FDA (the PLUS Program). ¶ 57.

Despite knowledge of the above information, in November 2003, Defendant Geffer publically touted that Plenaxis "would be applicable to treat a large segment" of the patients taking hormonal therapy. ¶¶ 43, 108-109. Geffer further misrepresented that 15-30% of the \$1.2 billion hormonal therapy market would be eligible to take Plenaxis. *Id.* In other words, Geffer was estimating Plenaxis revenues of between \$100-300 million. Of course, since the entire market for Plenaxis consisted of only a fraction of the 7.3% prostate cancer patients exhibiting

severe symptoms, Gefter's statements had no basis in fact.³¹

Defendants made no attempt to amend Gefter's impossible revenue projections until January 30, 2004 when the Company stated that 2004 revenues from Plenaxis were estimated to be between \$10-20 million. ¶¶ 112-114. However, this projection was equally implausible based on the Company's internal sales quotas. All forty Plenaxis sales representatives were expected to acquire 10 patients within a five month period. ¶ 67. Even assuming that all 400 patients were immediately acquired at the beginning of the five month period (a highly unlikely event), and that every patient used six vials of Plenaxis at \$700.00 a vial, total revenues for the five month period would only be \$1.68 million. ¶ 67. Thus, even under these highly improbable circumstances (*i.e.* 100% sales quotas achieved by all salesman with all patients using the maximum dosage), results in total yearly revenue equaling about half Defendants' low end revenue projection.³² Indeed such a scenario is implausible since a competing drug, Lupron, which doctors had been prescribing for fifteen years provided a significantly better profit margin than Plenaxis and also did not have a black box warning and produced fewer side-effects. ¶¶ 50-52, 56.

Courts have consistently held "that a defendant does not place itself beyond the reach of the securities laws merely by disclosing information that is predictive in nature. For example, when necessary, courts have readily conceded that predictions may be regarded as 'facts' within the meaning of anti-fraud provisions of the securities laws." *Isquith v. Middle South Utilities, Inc.*, 847 F.2d 186, 203 (5th Cir.), *cert. denied*, 488 U.S. 926 (1988).

³¹ Praecis's Chief Medical Officer provided the same false and misleading information during a conference call with investors and analysts. ¶ 108.

³² Incredibly, Defendants contend that Plaintiffs engage in "fuzzy" math in arriving at these figures even though the numbers are completely skewed in Defendants' favor. In fact, as Defendants concede, by the third quarter, total revenues totaled only about \$2 million which is in line with Plaintiffs' calculation. Def. Mem. at 26, fn. 21.

- **Defendants are presumed to know facts critical to Praecis's operations.**

Both the Company and the Individual Defendants are presumed to know facts critical to the Company's operations. The CAC establishes a strong inference that Praecis and its key officers/directors, defendant Geffer (Chairman and CEO of Praecis), defendant Heiden (President and COO of Praecis), defendant McLaughlin (CFO and VP of Praecis), and defendant English (CFO and Treasurer of Praecis) knew or were reckless in not knowing about the fraudulent public statements concerning Plenaxis. Facts critical to a business's core operations or an important transaction generally are so apparent that their knowledge may be attributed to the company and its key officers. Epstein v. Itron, Inc., 993 F. Supp. 1314, 1326 (E.D. Wash. 1998) (complaint adequately alleged a strong inference of scienter based on facts critical to a business's core operations and important transactions); Guerra v. Teradyne Inc., 2004 WL 1467065 * 27 (D.Mass. Jan 16, 2004) (when there is an affirmative misrepresentation made about facts relating to significant parts of the company's business such that the defendants' allowance of such misinformation to stand must have been intentional and for the purpose of deceit); Cosmas v. Hassett, 886 F.2d 8, 12-13 (2d Cir.1989).³³

The misleading facts, as alleged in the CAC, are precisely the types of "core" or "important transactions" that may be presumed to be known by the company and its key officers. Most importantly, the CAC focuses on alleged fraudulent and misleading statements during the Class Period concerning Plenaxis, the **only** drug Praecis had on the market. Indeed, the Company described Plenaxis as its "leading product." ¶ 42. Plenaxis represented the

³³ See also In re Cell Pathways Sec. Litig., 2000 U.S. Dist. LEXIS 8584 at *23 (E.D. Pa. June 21, 2000) ("where the alleged fraud relates to the core business of the company, knowledge of the fraud may be imputed to the individual defendants"); Lindelov v. Hill, 2001 U.S. Dist. LEXIS 10301 (N.D. Ill. July 20, 2001) ("it is strongly inferential that every officer or director . . . either had the knowledge of the feasibility of launching OneMedPlace.com in 1999 or, if not, that his failure to have such knowledge equated to reckless disregard").

Company's only source of sales revenue. ¶ 112. Moreover, the substantial majority, if not all the Praecis's sales personnel were dedicated to selling only Plenaxis. ¶ 120. It can hardly be disputed that information concerning Plenaxis represented facts critical to the Company's core operations. Therefore, the fact that Defendants allowed the public misrepresentations of Plenaxis to stand, must have been intentional and for the purpose of deceit. Guerra v. Teradyne Inc. 2004 WL at * 27.

• **The individual defendants' jobs were in potential jeopardy.**

During the Class Period, the Individual Defendants were the controlling persons of Praecis. ¶157. As such, Defendants were the ones who approved, and in some cases personally published, the various revenue expectations throughout the Class Period. ¶¶107,109,112-113,118,121,127,132. While Defendants' primary personal financial motives are clear, Defendants also needed to continue issuing the false and misleading statements because "their jobs were in jeopardy if the goals were not met." Aldridge, 284 F.3d at 84. Indeed, during the Class Period, Plenaxis was the Company's first and only product commercially available product, and the future viability of the Company was heavily dependant on the success or failure of Plenaxis.

In light of the total mix of information, Plaintiffs have adequately pled scienter under the PSLRA.

IV. THE COMPLAINT ADEQUATELY ALLEGES LOSS CAUSATION

Following the Supreme Court's decision in Dura Pharmaceuticals, Inc. v. Broudo, 125 S.Ct. 1627, 1631-32 (2005), a plaintiff must plead that the defendant's fraud proximately caused the plaintiff's economic harm. In Dura, the Supreme Court confirmed that loss causation requires a causal connection between the loss allegedly suffered by the plaintiffs and the misrepresentations of which they complain, holding that artificial inflation alone is insufficient to

plead loss causation. Dura, 125 S. Ct. at 1634. The Supreme Court took care, however, to distinguish between what was needed to prove loss causation, and what was needed to plead loss causation. Compare Dura, 125 S. Ct. at 1632-33 (Part A of the decision discussing the standard of proof to be made at trial) to id. at 1634 (Part B of the decision discussing the pleading standard). Specifically, Justice Breyer, speaking for a unanimous Court, explained:

We concede that the Federal Rules of Civil Procedure require only “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. Rule Civ. Proc. 8(a)(2). And we assume, at least for argument’s sake, that neither the Rules nor the securities statutes impose any special further requirement in respect to the pleading of proximate causation or economic loss. . . the “short and plain statement” must provide the defendant with “fair notice of what the plaintiff’s claim is and the grounds upon which it rests.” Conley v. Gibson, 355 U.S. 41, 47 (1957).

Id.

Further elaborating on the minimal burden a plaintiff must meet to plead loss causation, the Supreme Court stated:

We concede that ordinary pleading rules are not meant to impose a great burden upon a plaintiff. Swierkiewicz v. Sorema N.A., 534 U.S. 506, 513-515 (2002). But it should not prove burdensome for a plaintiff who has suffered an economic loss to provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind.

Id. (emphasis added).

Thus, the pleading standard established by Dura for loss causation is simple and straightforward: a plaintiff must allege facts sufficient to provide “a defendant with some indication of the loss and the causal connection that the plaintiff has in mind.” Id. (emphasis added).

The Supreme Court held that the complaint before it in Dura “fails this simple test” because it “contains only one statement that we can fairly read as describing the loss caused by the defendants’ ‘spray device’ misrepresentations.” Id. Namely, the Dura complaint simply

alleged that the plaintiffs paid an artificially inflated price and “suffered damages.” *Id.* (internal quotations omitted). The plaintiffs in *Dura* made no further attempt to provide a causal connection between losses suffered and defendant’s conduct. Thus, the Supreme Court noted, the defendants were not provided “with notice of what the relevant economic loss might be or of what the causal connection might be between that loss and the misrepresentation concerning *Dura*’s ‘spray device.’” *Id.* (emphasis added). Plaintiffs in this case pled much more than what was pled in *Dura*, and have put Defendants on notice of both the “relevant economic loss” and the “causal connection” they had in mind. *See Stumpf v. Garvey (In re Tycom Ltd. Sec. Litig.*, 2005 WL 2127674, *12 (D.N.H. Sept. 2, 2005) (plaintiff adequately alleged loss causation where revelation of true facts regarding bandwidth caused stock prices to decline across the entire telecommunications market); *Sekuk Global Enterprises v. KVH Industries, Inc.*, 2005 WL 1924202, *17 (D.R.I. Aug. 11, 2005) (loss causation adequately alleged where complaint alleged that the price of stock dropped after the truth regarding the defendants’ misrepresentations regarding expected sales and lower sales forecasts became known).³⁴

Plaintiffs in this case have alleged that the *subject* of Defendants’ fraudulent statements

³⁴ Defendants rely heavily on the Second Circuit’s decision in *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161 (2d. Cir. 2005) to argue that Plaintiffs have failed to allege loss causation. Defendants’ reading of *Lentell*, however, misses the point. The Court in *Lentell* found that the plaintiffs failed to plead loss causation because the Complaint contained “no allegation that the market reacted negatively to a corrective disclosure regarding the falsity of [the defendant’s statements] and no allegation that [the defendant] misstated or omitted risks that did lead to the loss.” *Id.* at 175 (emphasis added). Furthermore, the Court noted research reports which were “full of (unchallenged) analysis . . . suggesting that [the investments] were volatile investments, and therefore subject to sudden and substantial devaluation risk.” *Id.* at 176.

The facts of this case are distinguishable from the facts of *Lentell*. The previously disclosed risks which the *Lentell* court determined precluded a showing of loss causation clearly communicated that the investments were “volatile” and subject to “sudden and substantial devaluation risk.” *Id.* at 176. In this case, the purported previously disclosed risks identified by Defendants are no where near the level of disclosure present in *Lentell*. *See* Def. Mem. at 33. The statements do not constitute prior disclosures, and Defendants cannot reasonably contend that the statements were “substantial indicia of the risk that materialized” and “unambiguously apparent on the face of the disclosures alleged to conceal the very same risk.” *Lentell*, 396 F.3d at 177. Rather, the alleged disclosures are mere cryptical allusions to factors that “may affect market acceptance;” there is nothing in the alleged prior disclosures that suggests the Plenaxis market was “volatile” or faced a “substantial devaluation risk.” *Id.* at 176.

or omissions, i.e. the marketability of and FDA restrictions on Plenaxis as well as revenue projections, was the cause of the actual loss suffered. Like the plaintiff in Stumpf and Sekuk, supra, Plaintiff's showing that their losses were fairly attributable to the revelation of the true state of the Plenaxis market provides the causal link required by Dura. Specifically, Praecis stock increased 14% following first-year sales forecasts ¶3; Plaintiffs allege artificial stock price inflation upon false and misleading forecasts and omissions ¶3; Praecis stock suffered a 25.8% decline on Dec. 6, 2004, when Defendants withdrew all guidance on sales and revenue and stated its plan to re-launch Plenaxis under a new sales model. ¶ 135. See Stumpf, supra, at 12; Sekuk, supra, at *17. Also, even if this Court determines that some Plenaxis risks were disclosed, Plaintiffs still may recover for harm caused by the materialization of facts that were concealed.³⁵ See Lentell, supra, at 177 citing Suez Equity, 250 F.3d at 97-98.

Finally, to the extent that Defendants' argument infers that the stock price drops were due to some intervening event other than the materialization of the truth behind Defendants' misrepresentations, such determination is a question of fact not properly decided in a 12(b)(6) motion to dismiss. See Stumpf, supra, at *13, citing Lentell, supra, at 174. Accordingly, because the Complaint shows that the stock price went up on Defendants' misleadingly good news and fell upon disclosure of the concealed problems with Plenaxis, Plaintiffs have adequately alleged loss causation. Defendants' Motion to Dismiss for failure to plead loss causation, therefore, should be denied.

V. PLAINTIFFS' CONSOLIDATED AMENDED COMPLAINT STATES A CLAIM FOR CONTROL PERSON LIABILITY

To make a prima facie showing under Section 20(a), a plaintiff must merely allege: (i) a

³⁵ The Complaint alleges, and Defendants ignore, specific significant facts which were known, yet concealed, during Defendants' initial forecasts regarding the market for Plenaxis: "(i) that primary purchasers, urologists, lacked the necessary distribution system to purchase Plenaxis; (ii) Praecis's pricing structure offered the target physicians ... little opportunity to profit ...; (iii) the 30 minute monitoring period further decreased urologists' profits, if any from Plenaxis ...; (iv) Plenaxis's 'black box' warning label also significantly increased urologists treatment and malpractice concerns, particularly in light of the fact that the existing competing medications used to treat prostate cancer bore no such warning labels, had been effectively prescribed for fifteen years, and could be prescribed to a much larger group of prostate cancer patients." Compl. ¶¶ 3, 103.

primary violation by the controlled person, and (ii) control of the primary violator by each individual defendant. In re Parmalat Securities Litigation, 375 F.Supp.2d 278, 307 (S.D.N.Y. 2005); see also Chalverus, 59 F. Supp. 2d at 236; In re PLC Systems, Inc. Sec. Litig., 41 F. Supp. 2d 106, 121-22 (D. Mass. 1999).

Defendants do not deny that they were control persons of Praecis but instead argue that there was no underlying violation. Specifically, Defendants contend that Plaintiffs must also plead “culpable participation” on the part of the Individual Defendants in order state claim under Section 20(a). Def. Mem. at 34. However the First Circuit recently held that a Section 20(a) claim is not insufficient absent an allegation of culpable participation on the part of the defendants. In re Stone & Webster, Inc., Securities Litigation, 424 F.3d 24, 26-27 (1st Cir. 2005); in accord In re Parmalat Securities Litigation, 375 F.Supp.2d at 308.

Here, Plaintiffs have made a prima facie showing of Section 20(a) liability. First, the CAC more than adequately pleads violations of Section 10(b) and Rule 10b-5 as to all of the Defendants. Second, the CAC adequately alleges that the Individual Defendants, who were all insider officers intimately involved in the day-to-day activities of Praecis are control persons of the Company. ¶¶ 157-158.

It is axiomatic that “a court should deny a motion to dismiss a Section 20(a) claim when the defendants themselves made the allegedly false and misleading statements.” Chalverus, 59 F. Supp. 2d at 236-37 (citing In re PLC Sys., Inc. Sec. Litig., 41 F. Supp. 2d 106 (D. Mass. 1999)). Here, several of the misleading statements alleged by Plaintiffs are quotes directly attributable to Individual Defendants Gefer, Heiden and McLaughlin. ¶¶ 107, 109, 112-113, 118, 121, 127, 132. As demonstrated above, the Complaint more than adequately pleads violations of Section 10(b) and Rule 10b-5 as to all of the Defendants, thus Defendants’ motions to dismiss the Complaint’s Section 20(a) claims should be denied.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request this Court deny Defendants’ motion

to dismiss in its entirety. In the alternative, if the Court is inclined to grant the motion, Plaintiffs respectfully request leave to amend.³⁶

Dated: October 24, 2005

Respectfully submitted,

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³⁶ Since filing the CAC, Plaintiffs have engaged in further investigation and uncovered additional information which bolsters their allegations. If this Court dismisses the CAC with leave to amend, Plaintiffs will have new, additional factual information which will further prove Defendants' violations of the federal securities laws.